K110375
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FEB 2 3 2012

510(k) SUMMARY

Title: **Blueshine's GOLD series**

Submitter: Blueshine srl via Querini,27 30171, Mestre Venezia Italy
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Contact: Chiara Ricci
C.E.O.

Date Prepared: Dec. 01, 2011

Device Trade Name: Blueshine's GOLD series

Common Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Name: Instrument, surgical, powered, laser
GEX
21 C.F.R. 878.4810

Predicate Devices:

- Quanta System S.p.A. Diode Medical Laser Family **(K072034)**
- Osyris, Pharaon Lipo **(K073617)**
- Pinpointe, Pinpointe Footlaser **(K093547)**

Summary of Onychomycosis Clinical data

Abstract: A 6-month follow-up study was conducted on 48 patients who received laser treatment for onychomycosis with Gold Series 980 Diode Laser (BlueShine, Venice - Italy).
Objective To examine long-term cure and relapse rates after treatment with a 2 millisecond-pulse 980 nm near-infrared laser in onychomycosis.
Setting Two private practices in Padua and Venice, Italy.
Subjects & Methods The study population comprised 48 patients (31 male & 17 female) aged 23 to 79 years with a clinical and mycological diagnosis of onychomycosis.
The Laser treatment consisted of 3 /4 sessions with 30 days interval. Each nail was treated with 2 alternating passes of laser pulses to cover the full nail, one pass applied vertically down each nail and the second applied

horizontally using defocused hand piece with 3 mm spot size.
The BlueShine Gold Series 980 Diode Laser has proven highly efficient against Onychomycosis. This protocol gives excellent results on almost all the nails treated and in a short time span.
The procedure is simple and quick with no noticeable side effects and complications.
Despite the high success rate, our laser treatment is not a definitive cure for onychomycosis. Therefore and because it can recur, preventative maintenance treatments might be recommended every 6 months.
The use of Blueshine Gold Series diode Laser on patients affected by Onycomycosis with different pathologies, has a significant, positive results.
On the 48 nails we found that , totally, 93,75 % have improved at least for 1/3 of the nail plate and no one was worse. 6,25 % were unchanged.
On the total eligible toenails (48) 45 presented some improvement and, much more important, 37 of these (77,09) showed complete clear nails, while just 8 presented middle or moderate clear.

First session % fungus

50-75	10(21%)
75-90	10 (21%)
>90	28 (58%)
Total	48 (100%)

All nails are checked visually and classified as:

1. Unchanged means there were no result or the nail were missed or < 1/3;
2. Middle cleared means that the improvement was 1/3 to 2/3;
3. completely cleared means that the improvement was > 2/3.

Results

Unchanged	3 (6%)
Middle clear	8 (17%)
Complete clear	37 (77%)
Total	48 (100%)

Intended Use / Indications for Use:

980nm Wavelengths

The Blueshine GOLD series , (and the fiber delivery systems and accessories used to deliver laser energy), is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, neurosurgery, general surgery, genitourinary surgery (urology), thoracic surgery, gynecology (GYN), pulmonology, ophthalmology, orthopedics, otolaryngology (ENT) and podiatry.

The Blueshine GOLD series Laser is indicated for use in the performance of specific surgical applications in gastroenterology, neurosurgery, general surgery, genitourinary surgery (urology), thoracic surgery, gynecology (GYN), pulmonology, ophthalmology, orthopedics, otolaryngology (ENT) and podiatry as follows:

Gastroenterology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include: hemostasis of esophageal varices; palliation of malignant dysphagia; palliative ablation of obstructive neoplasms; hemostasis of colonoscopy.

Neurosurgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include: tumors adjacent to the spinal cord; tumors adjacent to the cortex.

General Surgery

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein. The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include: Laparoscopic: appendectomy; cholecystectomy; bowel resection. Open: mastectomy; reduction mammoplasty; breast biopsy; rectal and anal hemorrhoidectomy; bowel resection; colectomy; cholecystectomy; liver resection; condyloma; thyroidectomy; thoracotomy; cavernous hemangioma.

Genitourinary (Urology)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include: Transurethral: transurethral incision of the prostate (TUIP); bladder

tumors; bladder neck incisions; urethral strictures; exterior sphincterotomy. Laparoscopic lymphadenectomy. Open: condyloma; circumcision; benign and malignant lesions of external genitalia

Thoracic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection; coagulation of blebs and bullae; adhesiolysis; pericardiectomy; mediastinal and thoracic lesions and abnormalities; mediastinal lymph node dissection; hemostasis; thoracotomy.

Gynecology (GYN)
The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic excision/lysis of adhesions; endometrial lesions, including ablation of endometriosis; laparoscopic assisted hysterectomy (LAVH); laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy; ovarian drilling; tubal fimbrioplasty; appendectomy. Open: conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN; condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

Pulmonology
The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

Ophthalmology
The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics; open DCR; endo-nasal DCR; tumor excision and biopsy; eyelid reconstruction; blepharoplasty.

Orthopedics
The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: Open: Dissect and coagulate.

Otolaryngology (ENT)
The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus: turbinectomy and

turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy; Laryngo-tracheal: removal of vocal cord/fold nodules, polyps and cysts;arytenoidectomy; tracheal stenosis; Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemi glossectomy; Head & Neck: tumor resection on oral, subfacial and neck tissues; parathyroidectomy; thyroidectomy.

Podiatry

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy Periungual and subungual warts, Plantar warts, Neuromas. The Gold Series is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T mentagrophytes, and/or yeasts Candida albicans, etc.).

In addition the Blueshine GOLD series Laser is intended for **Laser Assisted Lipolysis**

Technological Characteristics:

The GOLD series Laser is designed with 4 major subsystems: (1) an external structure; (2) power electronics; (3) display with control electronics, which controls the power electronics, the user interface and the laser source temperature via a thermostat board; and (4) the laser system with an opto-mechanical block composed of the laser source, the Peltier cooling system with dissipater and fans, the fiber launching system, the red diode aiming beam, and the power calibration system. The external accessories include separate optical fibers and hand pieces for dental, dermatological and surgical applications, or for endovascular applications. The fiber is connected to the system through an SMA 905 socket on the front panel. In addition to the four subsystems, the Diode Laser Family incorporates several safety features, including a remote interlock and a key switch..

The Blueshine laser was tested and conformed with the following standards:

- IEC 60601-1-1 Ed 2.0 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Ed 2.1 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60825-1 (2003-2): Safety of laser products – Part 1: Equipment classification, requirements and user's guide

Substantial Equivalence:

The Blueshine GOLD series Laser is as safe and effective as the predicate devices. The GOLD series Laser has the same intended uses, and similar indications for use, technological characteristics, and principles of operation as the predicates. The minor technological differences between the GOLD series Laser and its predicates raise no new issues of safety or effectiveness. Thus, the GOLD series Laser is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Blueshine Srl
% Ms. Chiara Ricci
Via Querini, 27 - 30171
Mestre Venezia, Italy

Re: K110375
Trade/Device Name: Blueshine GOLD Series
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: PDZ, GEX
Dated: February 23, 2012
Received: February 23, 2012

Dear Ms. Ricci:

This letter corrects our substantially equivalent letter of February 23, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) : K110375

Device Name: Blueshine GOLD series

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Neil R Ogden for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Prescription Use: __X__ AND/OR Over-The-Counter Use: ___
(Part 21 C.F.R. 801 Subpart D) (Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number K110375